



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,888	08/01/2003	Joerg Martin Bentzien	9/254	3053

28509 7590 05/16/2005

MICHAEL P. MORRIS
BOEHRINGER INGELHEIM CORPORATION
900 RIDGEBURY ROAD
P O BOX 368
RIDGEFIELD, CT 06877-0368

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/632,888

Applicant(s)

BENTZIEN ET AL.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

2D

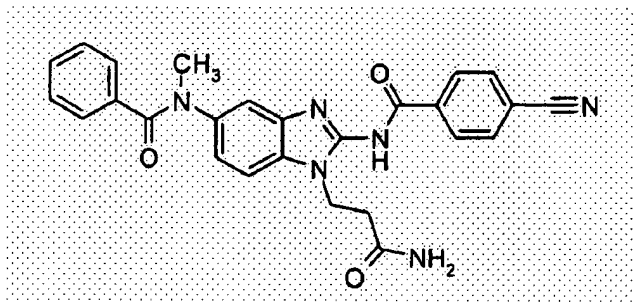
Art Unit: 1626

DETAILED ACTION

Claims 1-16 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I, and elected the species of the fourth compound on page 35 of the instant specification (reproduced below), in the reply filed on October 21, 2004 was acknowledged in the previous Office Action.



The requirement was deemed proper and made FINAL in the previous Office Action.

Claims 10-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being

Art Unit: 1626

drawn to a nonelected invention. Election was made without traverse in the reply filed on October 21, 2004.

Rejections made in the previous Office Action that do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1626

In claim 1, since the definition of the R_4 variable has been amended, it would appear that the R_7 variable, and both of its definitions, are no longer needed in the claim. See claims 2-4 for same. Claim 6 lacks antecedent basis from the claims in which it depends since the definition of the R_4 variable has been amended in independent claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frenkel et al. {U.S. Pub. No. 2003/0144286}, Craig et al. {U.S. Pat.

Art Unit: 1626

3,336,191}, Craig et al. {U.S. Pat. 3,401,171} and Smith Kline & French Laboratories {GB 1,122,957}, each taken alone or in combination with each other when similar utilities are asserted.

*Determination of the scope and content of the prior art (MPEP
§2141.01)*

Applicants claim benzimidazole compounds. **Frenkel et al.** (Formula I on pages 6-7; Formula IIa on pages 8-9; Formula IV on page 10; Formula VII on page 11; Formula VIIa on page 12; the compositions on page 13, paragraphs [0140] through [0143]; the different forms of the compounds on page 5, paragraphs [0053] through [0057]; and especially Compound 30 in Figure 1e - Sheet 5 of 13), **Craig et al.** '191 (column 1, lines 15-48; column 5, lines 18-73; and especially the compounds in column 2, lines 34, 35, 47, 55 and 56, Example 18 in column 9 and Example 30 in column 13), **Craig et al.** '171 (column 1, lines 32-69; column 5, lines 28-41; and especially the compound in column 3, lines 7-8, and

Art Unit: 1626

Example 22 in column 9) and **Smith Kline & French Laboratories** (page 1, columns 1 and 2; page 3, column 2, lines 103-110; page 4, column 1, lines 1-11; and especially Example 22 on page 8) each teach benzimidazole compounds that are structurally similar to the instant claimed compounds.

Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar

Art Unit: 1626

compounds would possess similar activity (e.g., anti-inflammatory).

One skilled in the art would thus be motivated to prepare compounds embraced by the prior art to arrive at the instant claimed compounds with the expectation of obtaining additional beneficial compounds which would be useful in treating, for example, inflammatory disorders. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Response to Arguments

Applicants' arguments filed February 7, 2005 have been fully considered. Applicants argue that the prior art of record, either alone or in combination, does not teach or suggest all the limitations of the instant claims.

Art Unit: 1626

Applicants' arguments have been considered but have not been found persuasive. As stated above, Applicants claim benzimidazole compounds. Frenkel et al., Craig et al. '191, Craig et al. '171 and Smith Kline & French Laboratories each teach benzimidazole compounds that are structurally similar to the instant claimed compounds. The difference being that the instant claimed compounds are generically described in the prior art.

Applicants argue that the compounds pointed out in the previous Office Action to establish the prior art rejections are not present in Frenkel et al.'s provisional application 60/327,818 and therefore, the specie in U.S. Pub. No. 2003/0144286 of Frenkel et al. are not afforded the benefit of the filing date of the provisional application, which is October 9, 2001. Applicants also argue that the provisional application of Frenkel et al. does not teach synthetic examples for making such compounds.

In response, Compound 30 in Figure 1e (Sheet 5 of 13) of Frenkel et al. was pointed out in the previous Office Action to establish rejections under 35 USC §§102(e) and 103. Applicants' allege that Compound 30 is not present in the provisional application (60/327,818) of Frenkel et al. Compound 30 is found in Figure 1e of the provisional application of Frenkel et al. However, Compound 30 of Frenkel et al. does not anticipate the currently amended claims. Further, the synthesis routes to the compounds found in the provisional application of Frenkel et al. is discussed at the top of page 22 of the provisional application of Frenkel et al.

Applicants argue that: (1) Craig et al. '191, Craig et al. '171 and Smith Kline & French Laboratories teach that their benzimidazole compounds possess antihelmintic activity whereas the instant claimed compounds possess anti-Itk kinase; (2) each of Craig et al. '191, Craig et al. '171 and Smith Kline & French

Art Unit: 1626

Laboratories teach an infinite number of compounds with preferred embodiments and specie diverging structurally from those of the instant claims; and (3) motivation in the prior art is not present in view of the structural divergence combined with the different compound activities.

All of Applicants' arguments have been considered but have not been found persuasive. There is no requirement that the prior art must suggest that the claimed product will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. In re Dillon, 16 U.S.P.Q. 2d 1897, 1904 (Fed. Cir. 1990). Further, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 148 USPQ 507,

Art Unit: 1626

510 (CCPA 1966). Additionally, the motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., anti-helminthics). For all the reasons given above, the instant claimed compounds would have been obvious to one skilled in the art.

The elected the species of the fourth compound on page 35 of the instant specification is not allowable over the art of record. See Frenkel et al. {U.S. Pub. No. 2003/0144286}.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action.

Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

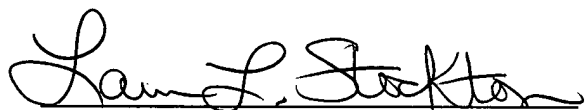
Any inquiry concerning this communication or earlier communications from the examiner should be

Art Unit: 1626

directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

May 4, 2005